REMARKS

Status of the claims

Claims 19-23 and 30-33 are currently pending.

Claims 19, 22, 23, 30, and 31 stand rejected under 35 U.S.C. §112, second paragraph as being indefinite.

Claims 19-23 and 30-33 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over

(1) claims 1, 3, 10, 11, 21-24, 28, and 29 of copending U.S. Patent App. No. 10/632,737 (U.S. Patent Pub. No. US2004/0105884, Attorney ref. PC27638, "US '884");

(2) claims 1, 4, 6-8, 14, 25-28, 32, and 33 of copending U.S. Patent App. No. 10/633,390 (U.S. Patent Pub. No. US2004/0105883, Attorney ref. PC27637, "US '883"); and

(3) claims 19-21, 23, and 26-31 of copending U.S. Patent App. No. 10/633,102 (U.S. Patent Pub. No. US2004/0131670, Attorney ref. PC27433, "US '670").

Claims 19-23 and 30-33 stand provisionally rejected under §103(a) as unpatentable over US '884 and separately as unpatentable over US '883.

Claims 19, 20, 22, 23 and 30-32 stand rejected under §103(a) as unpatentable over Satoshi et al., EP 0 695 544 ("EP '544") in view of Berthel et al., U.S. Patent Publication No. US2003/0219477 ("US '477").

Claims 19, 20, 22, 23 and 30-33 stand rejected under §103(a) as unpatentable over EP '544 in view of US '477 and Black et al., U.S. Patent No. 5,733,909 ("US '909").

Claims 30 and 31 have been cancelled. Claims 19 and 23 have been amended to require that the sulfite compound is sodium metabisulfite, sodium bisulfite, or sodium thiosulfate. Support for this amendment may be found, for example, at paragraph [0028]. Claim 22 has been amended to specify that the fill material further comprises an amine agent. Support for this amendment may be found, for example, at paragraph [0086]. Claim 23 has been amended to specify that the fill material further comprises sodium metabisulfite, sodium bisulfite, or sodium thiosulfate. Support for this amendment may be found, for example, at paragraph [0087].

35 U.S. C. §112, second paragraph rejections

Reconsideration is respectfully requested of the rejection of claims 19, 22, 23, 30, and 31 under §112, second paragraph as being indefinite. Claims 30 and 31 have been cancelled, rendering moot their rejection under this section.

The Office asserts that claim 19 does not clearly state the metes and bounds of the claim because of the term "and/or". Applicants respectfully disagree. Claim 19, as amended, is directed to a pharmaceutical dosage form comprising a fill material sealed in capsule shells, wherein the capsule shells

comprise sodium metabisulfite, sodium bisulfite, or sodium thiosulfate, and wherein said sodium metabisulfite, sodium bisulfite, or sodium thiosulfate is present in an amount sufficient to inhibit gelatin cross-linking and/or pellicle formation in the capsule shells upon storage of the dosage form; wherein the fill material comprises celecoxib. Thus, claim 19 requires that the sodium metabisulfite, sodium bisulfite, or sodium thiosulfate is present in an amount sufficient to inhibit, in the capsule shells upon storage of the dosage form, three possible occurrences: (1) gelatin cross-linking, (2) pellicle formation, or (3) both gelatin cross-linking and pellicle formation. Claim 19, therefore, reads on a capsule shell comprising sodium metabisulfite in an amount sufficient to inhibit gelatin cross-linking but not sufficient to inhibit pellicle formation. Likewise, the claim reads on a capsule shell comprising sodium metabisulfite in an amount sufficient to inhibit pellicle formation but not sufficient to inhibit gelatin cross-linking. And finally, claim 19 reads on a capsule shell comprising sodium metabisulfite in an amount sufficient to inhibit both gelatin cross-linking and pellicle formation. The metes and bounds of the claim are clearly stated, and thus claim 19 satisfies §112, second paragraph.

Claim 22 depends from claim 19, and has been amended to specify that the fill material *further* comprises an amine agent. Thus, a dosage form according to claim 22 comprises a fill material that comprises celecoxib and an amine agent.

Similarly, claim 23, which also depends from claim 19, has been amended to specify that the fill material *further* comprises sodium metabisulfite, sodium bisulfite, or sodium thiosulfate. Thus, a dosage form according to claim 23 comprises a fill material that comprises celecoxib and sodium metabisulfite, sodium bisulfite, or sodium thiosulfate.

Provisional nonstatutory obviousness-type double patenting rejections

Reconsideration is respectfully requested of the provisional rejection of claims 19-23 and 30-33 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 10, 11, 21-24, 28, and 29 of US '884; claims 1, 4, 6-8, 14, 25-28, 32, and 33 of US '883; and claims 19-21, 23, and 26-31 of US '670. Claims 30 and 31 have been cancelled, rendering moot their provisional rejection under this doctrine.

According to PAIR, US '670 and US '883 have both been abandoned, thus rendering moot the provisional rejection based on these applications. Pending allowance of the instant application, Applicant will submit a Terminal Disclaimer to obviate the rejection based on US '884.

Provisional 35 U.S. C. §103(a) rejections

Reconsideration is respectfully requested of the provisional rejection of claims 19-23 and 30-33 under §103(a) as unpatentable over US '884 and separately as unpatentable over US '883. Claims 30 and 31 have been cancelled, rendering moot their provisional rejection under this section.

As acknowledged by the Office, the instant application was owned by, or subject to an obligation of assignment to, the same entity as US '884 and US '883. Thus, if US '884 and US '883 were prior art against the subject application only under §§102(e), (f), and/or (g), US '884 and US '883 would not

preclude patentability of the claims of the subject application under §103. See §103(c). However, according to the Office, US '884 and US '883 "additionally qualifies as prior art under another subsection of 35 U.S.C. 102, and, therefore, is not disqualified as prior art under 35 U.S.C. 103(c)." (The Office did not state under which subsection of §102 US '884 and US '883 qualify as prior art.) Applicants respectfully disagree.

Section 102(a) states that "a person shall be entitled to a patent unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent." US '884 and US '883 both published on June 3, 2004, which is after the filing date of the subject application. Thus, US '884 and US '883 are not prior art under §102(a).

Section 102(b) states that "a person shall be entitled to a patent unless the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." As noted above, both US '884 and US '883 published after the filing date of the subject application, and thus US '884 and US '883 are also not prior art under §102(b),

Neither of §§102(c) or (d) relate to prior US applications, and thus are not relevant to this provisional rejection.

Thus, US '884 and US '883 are not prior art against the subject application under any subsection of §102, and thus Applicants respectfully request that these provisional rejections be withdrawn.

35 U.S. C. §103(a) rejections

Reconsideration is respectfully requested of the rejection of claims 19, 20, 22, 23 and 30-32 under §103(a) as unpatentable over EP '544 in view of US '477. Reconsideration is also respectfully requested of the rejection of claims 19, 20, 22, 23 and 30-33 under §103(a) as unpatentable over EP '544 in view of US '477 and US '909. Claims 30 and 31 have been cancelled, rendering moot their rejection.

A *prima facie* showing of obviousness requires, *inter alia*, that the prior art references teach or suggest all the claim limitations. See MPEP §2143. Claim 19, as amended, requires capsule shells comprising sodium metabisulfite, sodium bisulfite, or sodium thiosulfate. Neither EP '544 nor US '477 do not describe dosage forms comprising sodium metabisulfite, sodium bisulfite, or sodium thiosulfate anywhere, and thus the Office has not shown that claim 19 is *prima facie* obvious in light of those references. Likewise, US '909 does not describe dosage forms comprising sodium metabisulfite, sodium bisulfite, or sodium thiosulfate, and thus the Office has not shown that claim 19 is *prima facie* obvious in light of the combination of all three references.

For the same reasons, the Office has not shown that claims 20, 22, 23, and 32, which depend from claim 19, are *prima facie* obvious in view of EP '544 and US '477, and the Office has not shown that claims 20, 22, 24, 32, and 33 (which also depends from claim 19) are *prima facie* obvious in view of EP '544, US '477, and US '909.

Conclusion

Applicants submit that the present invention is now in condition for allowance. Early allowance of all pending claims is respectfully solicited.

Respectfully submitted,

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